Commission Regulation (EU) No 8/2010 of 23 December 2009 concerning the authorisation of the serine protease produced by Bacillus licheniformis (DSM 19670) as a feed additive for chickens for fattening (holder of authorisation DSM Nutritional Products Ltd, represented by DSM Nutritional Products Sp.Z.o.o) (Text with EEA relevance)

COMMISSION REGULATION (EU) No 8/2010

of 23 December 2009

concerning the authorisation of the serine protease produced by *Bacillus licheniformis* (DSM 19670) as a feed additive for chickens for fattening (holder of authorisation DSM Nutritional Products Ltd, represented by DSM Nutritional Products Sp.Z.o.o)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[(1)], and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the preparation set out in the Annex to this Regulation. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of the enzyme preparation of serine protease produced by *Bacillus licheniformis* (DSM 19670) as a feed additive for chickens for fattening, to be classified in the additive category ‘zootechnical additives’.

(4) The European Food Safety Authority (the Authority) concluded in its opinion of 2 and 7 July 2009[(2)] that the enzyme preparation of serine protease produced by *Bacillus licheniformis* (DSM 19670) does not have an adverse effect on animal health, human health or the environment and that the use of that preparation can improve the performance of the animals. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of that preparation shows that the conditions for authorisation, provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised, as specified in the Annex to this Regulation.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘digestibility enhancers’, is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 23 December 2009.

For the Commission

The President

José Manuel BARROSO

ANNEX

Identification number of the additive	**Name of the holder of authorisation**	**Additive**	**Composition, chemical formula, description, analytical method**	**Species or category of animal**	**Maximum age**	**Minimum content**	**Maximum content**	**Other provisions**	**End of period of authorisation**
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers									
4a13	DSM Nutritional Products Ltd, represented by DSM Nutritional Products Sp.Z.o.o.	Serine protease EC 3.4.21.-	Additive composition: Preparation of serine protease (EC 3.4.21.-) produced by *Bacillus licheniformis* (DSM 19670) having a minimum activity of 75 000 PROT[a]/g Characterisation of the active substance: Serine protease (EC 3.4.21.-) produced by *Bacillus licheniformis*	Chickens for fattening	—	15 000 PROT	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. For safety reasons: breathing protection, glasses and gloves shall be used during handling.	13.1.2020

a 1 PROT is the amount of enzyme that releases 1 µmol of p-nitroaniline from 1mM substrate (Suc-Ala-Ala-Pro-Phe-pNA) per minute at pH 9,0 and temperature 37 °C.

b Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives

				(DSM 19670) Analytical method[b]: Colorimetric method measuring yellow complex para-nitroaniline (pNA) released by the enzyme from 'Suc-Ala-Ala-Pro-Phe-pNA' at pH 9,0 and at 37 °C						

a 1 PROT is the amount of enzyme that releases 1 µmol of p-nitroaniline from 1mM substrate (Suc-Ala-Ala-Pro-Phe-pNA) per minute at pH 9,0 and temperature 37 °C.

b Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives

(**1**) OJ L 268, 18.10.2003, p. 29.

(**2**) *The EFSA Journal* (2009) 1185, p. 1.

Changes to legislation:
There are outstanding changes not yet made to Commission Regulation (EU) No 8/2010. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Regulation revoked by S.S.I. 2022/288 Sch. 12 para. 3
- Regulations revoked by S.I. 2022/1129 Sch. 12
- Regulation revoked by S.I. 2022/1118 Sch. 12